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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,322	08/17/2001	James P. Beltzer	DYX-018.1 US	5654
26161	7590	06/30/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			CHISM, BILLY D	
			ART UNIT	PAPER NUMBER
			1654	
DATE MAILED: 06/30/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/932,322	<b>Applicant(s)</b> BELTZER ET AL.	
	<b>Examiner</b> B. Dell Chism	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-14, drawn to a BlyS binding polypeptide, classified in class 514, subclass 12, for example.
  - II. Claims 15-23, drawn to a bacteriophage expressing exogenous DNA encoding BlyS binding protein, classified in class 435, subclass 5, for example.
  - III. Claim 24, drawn to method of detecting a BlyS binding polypeptide, classified in class 514, subclass 12, for example.
  - IV. Claims 25 and 28, drawn to a method of purifying a BlyS binding polypeptide, classified in class 514, subclass 12, for example.
  - V. Claims 26-27, drawn to a BlyS binding polypeptide separation media, classified in class 514, subclass 12, for example.
  - VI. Claims 29-35 and 38, drawn to polynucleotides and DNA encoding a BlyS binding polypeptide, classified in class 435, subclass 6.
  - VII. Claim 36, drawn to a method of identifying a BlyS binding polypeptide, classified in class 514, subclass 12, for example.
  - VIII. Claim 37, drawn to a BlyS binding polypeptide affinity maturation library, classified in class 514, subclass 12, for example.
2. The inventions are independent or distinct, each from the other because:

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Groups I and II are products having different classification and are structurally and functionally independent and having different effects.

The product of Group I is neither made by nor used in the method Group III. Group III methods are for the detection of a BlyS binding polypeptide which wherein if the BlyS binding polypeptide is not present then there will be not detection.

The product of Group I and the method of purifying of Group IV are distinct wherein the product of Group I can be purified by other methods, i.e., various resins, various chromatographies, etc...

Groups I and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the product of Group I has separate utility such as immunoassays or molecular weight markers. See MPEP § 806.05(d).

Groups I and VI are related as product made and apparatus. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the product can be made via posttranslational modification, for example.

Groups I and VII are distinct inventions as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be use in a materially different process of using that product (MPEP §

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806.05(h)). In the instant case the proteins of Group I can be used for immunoassays and molecular weight markers, for example.

Groups I and VIII are independent products that have structural and functional differences with different effects.

Group II is independent of Groups III-IV and VII wherein the product of Group II is neither made by nor used in the method steps of Groups III-IV and VII.

Group II is independent of Groups V and VIII wherein the products of all groups have structural and functional differences with different effects.

Groups II and VI are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the product of Group VI can be made by PCR methods, for example.

Group III and Groups IV and VII independent method groups with different method steps requiring different components and having different end results.

Group III and Groups V-VI and VIII are independent wherein the methods of Group III neither use nor make the products of Groups V-VI and VIII.

Group IV is independent of Groups V-VIII wherein the method of Group IV neither makes nor uses the products of Groups V-VI or VIII. The methods of Groups IV and VII are independent wherein the methods steps require different components with differing effects.

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The product of Group V is independent from Groups VI-VIII wherein the product of Groups V is neither made by nor used in the method steps of Group VII. Group V is structurally and functionally different from the products of Groups VI and VIII with different effects.

Group VI is independent of Groups VII-VIII wherein the product of Group VI is neither made by nor used in the method steps of Group VII, and wherein Group VI is structurally and functionally different from the product of Groups VIII, having different effects.

Groups VII and VIII are independent because the method steps of Group VII neither make nor use the product of Group VIII.

3. Because these inventions are distinct or independent for the reasons given above, have acquired a separate status in the art as shown by their different classification, and because the search for one group would not necessarily be inclusive of a search of another group, thus being burdensome to the examiner, restriction for examination purposes as indicated is proper.
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter

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of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### *Conclusions*

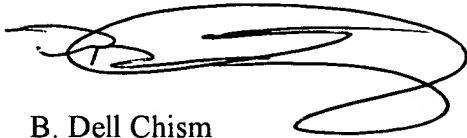
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 571-272-0962. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

\*\*\*

A handwritten signature in black ink, appearing to read "B. Dell Chism", with a large, stylized flourish extending from the end.

B. Dell Chism

28 June 2004

A handwritten signature in black ink, appearing to read "Christopher R. Tate", with a large, stylized flourish extending from the end.  
**CHRISTOPHER R. TATE**  
**PRIMARY EXAMINER**